REMARKS

Upon entry of the present amendment, claims 2, 7-26, 29-34, 36, 38, 39, 44-56, 59, 60, and 105-124 will be pending.

Claims 2, 10-13, 17-19, 29-33, 38-39, 49, 59, 105, 112, and 114-115 have been amended. Claims 2, 10-13, 17, 29-33, 38-39, 49, and 59 have been amended as described below in connection with Office's respective rejections.

Claim 105 has been amended for clarity and to provide that the claimed kit is selected to deliver substantially all of the beneficial agent in a controlled manner over a duration of less than about seven days. The amendment to claim 105 is fully supported by the specification as filed, for example, at page 5, paragraph [0011]; page 6, paragraph [00015]; and, FIG. 2, which depicts how an embodiment of the current invention, designated "Formulation 4", displays a release profile that is characterized as providing detectible blood plasma levels of beneficial agent prior to about day 7, and undetectably low blood plasma levels after this time. In comparison, another embodiment, designated "Formulation 3" provides detectible blood plasma levels of beneficial agent for as long as 28 days. The undetectable blood plasma levels observed after day 7 with respect to Formulation 4 are attributable to a substantially complete depletion of beneficial agent from that depot formulation, as contrasted with Formulation 3, which does not deliver an amount of its beneficial agent within the measured time period such as would result in undetectably low blood plasma levels of beneficial agent.

Claims 18-19, 38-39, 112, and 114-115 have been amended for clarity, specifically, to provide that the specified weight percentage of polymer pertains to the quantity of such polymer in the gel that is formed from the combination of the polymer and the solvent. These amendments are fully supported by the specification as filed, for example, at page 26, paragraph [00085].

New claims 122-124 have been added and are fully supported by the specification as filed, for example, at page 13, paragraph [00041].

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2, 7-26, 29-34, 36, 38, 39, 44-56, 59, 60, and 105-121 have been rejected under § 112, second paragraph for alleged indefiniteness.

In particular, the Office alleges that claims 2, 27, and 59 and their respective dependents are unclear to the extent that they claim a composition that is both injectable and a gel, the premise of the rejection being that the two characteristics are allegedly mutually exclusive. Applicants respectfully disagree, as it is widely recognized among those skilled in the art that, depending on such factors as the viscosity of the gel, the shear-thinning characteristics of the gel, and the size (gauge) of the injection needle, a "gel" is capable of flowing through a needle and being injected thereby. *See, e.g.*, U.S. Pat. No. 6,130,200 (assigned to the owner of the present application), which describes numerous embodiments of injectable gel compositions. The present application as filed describes some circumstances under which the instant gels may be injectable, for example, at paragraphs [000112]-[000113], pages 38-39, and provides numerous exemplary embodiments of injectable gels, for example, at paragraph [000136], pages 51-52. Applicants therefore submit that it is not unclear how a composition could be both a gel and injectable, and the rejection to the contrary is improper and should be withdrawn.

The Office states that claims 10-12, 17, 29-32, 49, and 59 "recite numerical values for polymer molecular weight without reciting the units" (6/28/07 Office Action at page 3). The rejected claims have been amended to provide that the numerical values for polymer molecular weight are measured in terms of Daltons. The same has been done with regard to claims 13 and 33, which also did not contain units of measurement. These amendments are fully supported by the specification as filed (see, for example, paragraph [000153], page 60, and FIGS. 11 & 12, describing poly(D,L-lactide-co-glycolide) (PGLA) having "8,000" and "10,000" molecular weight as "low molecular weight", which one skilled in the art would clearly recognize as corresponding to Daltons). Withdrawal of the instant rejection is respectfully requested.

The Office has also expressed its view that the phrase "wherein the lactic acid-based polymer comprises about [weight percentage value] of the composition" as used in claims 38-39 is unclear, and that the claims should be reworded. Applicants have amended claims 38 and 39 in accordance with the Office's suggestion. Withdrawal of the rejection of claims 38-

39 is respectfully requested. Applicants have also amended claims 18-19, 112, and 114-115 in accordance with the convention advocated by the Office.

The Office has maintained its argument that the term "lactic acid-based polymer" as used in claims 15, 17, 29, 30-33, 36, 38-39, 49, and 113-115 is unclear. Applicants respectfully disagree. The definitions provided by the instant specification at paragraph [00080] provides clear notice to the public of the boundaries of what constitutes infringement of the claims containing the term "lactic acid-based polymer": in sum, a composition that comprises a polymer that is based solely on lactic acid or a polymer that includes at least one lactic acid monomer will fall within the scope of the instant claims. There is no doubt that one skilled in the art would understand what this means, and in turn, what are the metes and bounds of the claims. *See* M.P.E.P. § 2173.02 ("the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope, and therefore, serves the notice function required by 35 U.S.C. 112, second paragraph"). The Office should not equate the breadth of the claim with indefiniteness; so long as the scope of the subject matter embraced by the claims is clear, then the claims comply with 35 U.S.C. § 112, second paragraph. *See* M.P.E.P. § 2173.04 (citing *In re Miller*, 441 F.2d 689 (C.C.P.A. 1971)). Because the scope of the subject matter embraced by the claims is clear, the rejection for alleged indefiniteness is inapposite and should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 2, 7-23, 29-34, 36, 38, 39, 44, 45, 47-56, 59, 60, and 105-121 have been rejected for alleged obviousness over WO 02/238185 to Dunn *et al.* ("the Dunn reference").

Applicants have amended claims 2, 29, and 59 to specify that the claimed composition delivers substantially all of the beneficial agent in a controlled manner over a duration of less than about seven days. This amendment is supported by the specification as filed, for example, at FIG. 2, which depicts how an embodiment of the current invention, designated "Formulation 4", displays a release profile that is characterized as providing detectible blood plasma levels of beneficial agent prior to about day 7, and undetectably low blood plasma levels after this time. In comparison, another embodiment, designated "Formulation 3" provides detectible blood plasma levels of beneficial agent for as long as 28 days. The undetectable blood plasma levels observed after day 7 with respect to Formulation

4 are attributable to a substantially complete depletion of beneficial agent from that depot formulation, as contrasted with Formulation 3, which does not deliver an amount of its beneficial agent within the measured time period such as would result in undetectably low blood plasma levels of beneficial agent. *See also* FIG. 1 (comparing Formulations 1 and 2); and, FIG. 4 (comparing Formulations 5 and 6).

The dosage forms disclosed by the Dunn reference do not deliver substantially all of a beneficial agent in a controlled manner over a duration of less than about seven days. The two embodiments cited by the Office, *i.e.*, those described in Example 6 of the Dunn reference, are characterized by release of only 74% and 75%, respectively, of loperamide HCl after three days following placement *in situ*. Furthermore, the Office has not demonstrated that claim 18, or any other portion of the Dunn reference that refers to compositions that are "formulated for administration about once per three days", teaches or suggests compositions that have a different release profile than the dosage forms described in Example 6 of the Dunn reference.

The Office suggests that because the Dunn reference provides that compositions may be formulated for administration about once per three days, release of drug from the composition would be "complete" after a three-day period (*see* 6/28/07 Office Action at page 5, first bullet point). However, there is no teaching or suggestion that the release profiles for the compositions disclosed in the Dunn reference can be equated with release of substantially all of the beneficial agent from the compositions; there is no evidence that the data disclosed by the Dunn reference refers to anything other than the amount of beneficial agent that is released prior to removal of the dosage form composition, in accordance with the protocol described in Example 6 at pages 22-23 ("On day 1 and day 3 implants were removed for subsequent HPLC analysis of loperamide."). The three-day period to which the Dunn reference refers only purports to pertain to the time between successive administrations, and the Dunn reference says nothing about whether the compositions are substantially depleted of drug during this time period. Rather, all indications from the Dunn reference are that, three days following implantation, no more than 75% of the beneficial agent is released from the dosage forms described therein.

Therefore, there is no disclosure in the Dunn reference of compositions that deliver substantially all of a beneficial agent in a controlled manner over a duration of less than about

seven days. For at least this reason, the rejection of the pending claims for alleged obviousness in view of the Dunn reference is improper and should be withdrawn. M.P.E.P. § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (all limitations set forth in a patent claim must be taught or suggested in the prior art to establish a *prima facie* case of obviousness).

Claims 24-26, 46, 55, and 56 stand rejected over the Dunn reference in view of WO 00/74650 to Brodbeck *et al.* ("the Broadbeck reference"). The Broadbeck reference does not remedy the shortcomings of the Dunn reference (described above) by teaching or suggesting a composition that delivers substantially all of a beneficial agent in a controlled manner over a duration of less than about seven days. Accordingly, a *prima facie* case of obviousness has not been presented, and the rejection of claims 24-26, 46, 55, and 56 under § 103(a) should be withdrawn.

Conclusion

The preceding represents a bona fide attempt to advance the present case to allowance. Applicants respectfully request an indication of allowability and an early Notice of Allowance. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 215-568-3100.

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